



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,654	11/12/2003	Sylvia A. Norman	GP141-03.UT	8961

21365	7590	06/21/2007
GEN PROBE INCORPORATED		
10210 GENETIC CENTER DRIVE		
Mail Stop #1 / Patent Dept.		
SAN DIEGO, CA 92121		

EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
06/21/2007	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdept@gen-probe.com  
kelleec@gen-probe.com  
belindao@gen-probe.com

<p align="center"><b>Office Action Summary</b></p>	<p><b>Application No.</b></p> <p align="center">10/712,654</p>	<p><b>Applicant(s)</b></p> <p align="center">NORMAN ET AL.</p>	
	<p><b>Examiner</b></p> <p align="center">Padmavathi v. Baskar</p>	<p><b>Art Unit</b></p> <p align="center">1645</p>	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 March 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-8,10-21,24-32 and 34-37 is/are pending in the application.
- 4a) Of the above claim(s) 7-8, 10-13, 15-16, 18- 21, 24-31 and 34-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6, 14, 17 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Amendment*

1. Applicant's amendment filed on 3/26/07 is acknowledged.

### *Status of claims*

2. Claims 1,3-8, 10-13, 15, 16, 16-21, 24, 27, 29, 31, and 32 have been amended .  
Claims 2, 9, 22, 23 and 33 have been canceled.  
New claims 34-37 have been added.  
Claims 1, 3-8, 10-21, 24-32 and 34-37 are pending in the application.  
Claims 1, 3-6, 14, 17 and 32 are under examination as an elected invention with respect to pagA target sequence.  
Claims 7-8, 10-13, 15-16, 18- 21, 24-31 and 34-37 are withdrawn from further consideration by he examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### *Claim Rejections - 35 USC § 102 maintained*

3. The rejection of claim 1 and 32, under 35 U.S.C. 102(e) as being anticipated by Lee et al (U.S. Patent No. 6,770,479) is maintained as set forth in the previous office action.

Applicant 3/26/07 states that the claim 1 and 32 have been amended as suggested by the examiner and therefore, the rejection should be withdrawn.

The argument has been fully considered but not found persuasive because the claim is drawn to a composition comprising synthetic oligonucleotide--- or a substantially complementary sequence or ----. Therefore, the opposite strand of said sequence is a substantially complementary sequence of about 40 nucleotides in a composition would hybridize to the target sequence.

Query Match 100.0%; Score 57; DB 3;  
Best Local Similarity 100.0%; Pred. No. 1.7e-22;  
Matches 57; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

```
Qy      1 GTGCTGGACCTACGGTTCCAGACCGTGACAATGATGGAATCCCTGATTCATTAGAGG 57
          ||||||||||||||||||||||||||||||||||||||||||||||||||||
Db     11 GTGCTGGACCTACGGTTCCAGACCGTGACAATGATGGAATCCCTGATTCATTAGAGG 67
```

### *New Claim Rejections - 35 USC § 112, first paragraph maintained*

4. The rejection of claims 1and 32 under 35 U.S.C. 112, first paragraph is maintained for the same reasons as set forth in the previous office action.

Applicant states that claims 1 and 32 have been amended to insert the oligonucleotide SEQ ID Nos. 1 to 8 and "substantially" before "complementary" . The specification defines the term "substantially

Art Unit: 1645

complementary"( page 10 ), provides guidance by citing well known methods described by Sambrook et al., Molecular Cloning, A Laboratory Manual, (2nd Ed., 1989), pp. 1.90-1.91, 7.37-7.57, 9.50-9.51, 11.12-11-13, and 11.47-11.57. Further description of hybridization conditions and methods appear in the specification at page 19, line 29 to page 20, line 22, and in the working examples at page 26, line 29 to page 42, line 23. Based on the definite target sequences specified in claims 1 and 32, the sizes of the synthetic oligonucleotides specified in claims 1 and 32, and the guidance provided in the specification including the working examples, there is no undue experimentation required.

Applicants arguments have been considered but not found to be persuasive because the specification defines "substantially complementary" as a nucleic acid sequence in one strand is less than 100% complementary to a nucleic acid sequence in an opposing strand, thus, complementary polynucleotides include not only the complement, which is completely complementary to the coding sequence of SEQ ID NO: 21/22/23/24 , but also includes a substantial number of species which lack significant /sufficient complementarity to SEQ ID NO: 21/22/23/24. Further description of hybridization conditions and methods in the specification at page 19, line 29 to page 20, line 22, and in the working examples at page 26, line 29 to page 42, line 23 use only SEQ ID NO: 21/22/23/24 but not substantially complementary sequences. Therefore, substantially complementary sequences under undefined hybridization conditions would not function as claimed because applicant is claiming a composition that comprise other reagents.

***New Claim Rejections - 35 USC § 112 second paragraph based on the amendment***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-6, 14, 17 and 32 are rejected as indefinite because claim 1 and 32 recite the term "substantially complementary". The term as defined by, the specification (page 10) indicates that a nucleic acid sequence in one strand is less than 100% complementary to a nucleic acid and thus does not provide a standard for ascertaining the requisite degree and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention as the claim is drawn to a composition.

***Remarks***

6. Claims 1, 3-6, 14, 17 and 32 are rejected.

This application contains claims 7-8, 10-13, 15-16, 18- 21, 24-31 and 34-37 , drawn to an invention nonelected . A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

**Conclusion**

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP ' 706.07(a). Applicant is reminded of

Art Unit: 1645

the extension of time policy as set forth in 37 CFR 1.136(a).

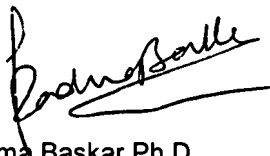
A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

8. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600



Padma Baskar Ph.D.



JEFFREY SIEW  
SUPERVISOR PATENT EXAMINER